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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,382	01/25/2001	Ian Richard Anselm Peak	8795-24 U1	6450

570 7590 01/17/2003

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EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	18

DATE MAILED: 01/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/771,382	PEAK ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-34* is/are pending in the application.

4a) Of the above claim(s) *26,27,29,33 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,28 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

FINAL ACTION

1. This Office Action is responsive to Applicant's amendment and response filed October 25, 2002. Claim 24 had been cancelled. Claims 25-32 have been amended. Claims 33-34 have been added. Claims 33-34 will not examined because they are drawn to non-elected species. It should be remembered that Applicant elected without traverse of Group II, claims 10-16, SEQ ID No: 11, residues 109-120 filed on April 22, 2002. Claims 26-27 and 29 were not examined because they are drawn to non-elected species. It should also be noted that the requirement to elected specific residues (i.e. residues 109-120) was withdrawn in the previous Office action. It should be noted that a typographical error was made on page 4, paragraph 5 of the previous Office action. The rejection under 112, first paragraph was for claims 24-25, 28 and 30-32, since claim 23 is a cancelled claim. It should be also noted that the Office failed to acknowledge the Applicant's claim to provisional application 60/177, 917 on the Office action Summary Sheet. The Office apologies these oversights.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Objection/Rejections Withdrawn

3. In view of Applicant's amendment the following Objections and Rejections have been withdrawn:

a)Objection to the specification, page 2, paragraph 2 of previous Office action.
b)Objection to the specification, page 2, paragraph 3 of previous Office action.
c)Rejection of claims 31-32 under 35 U.S.C. 112, first paragraph, pages 6-9, paragraph 7 of the previous Office action.
d)Rejection of claims 24 under 35 U.S.C. 112, second paragraph, page 9, paragraph 8 of the previous Office action.
e)Rejection of claim 31 under 35 U.S.C. 112, first second, page 9, paragraph 9 of the previous Office action.
f) Rejection of claim 30 under 35 U.S.C. 102(b), pages 11-12, paragraph 11 of the previous Office action.
g) Rejection of claim 30 under 35 U.S.C. 102(b), page 12, paragraph 12 of the previous Office action.

Objections/Rejection Maintained

4. The objections to the drawing are maintained for the reasons set forth on page 4, paragraph 4.

The objection was on the grounds that the drawings are objected to by the Draftsman under 37 CFR 1.84 or 1.152.

Applicant urges that they have provided substitute drawings. This objection can be obviated by the submission of new formal drawings. See the Draftsman's Attachment.

5. The rejection under 35 U.S.C. 112, first paragraph is maintained for claims 25, 28 and 30-32 for the reasons set forth pages 4-6, paragraph 5 of the previous Office Action.

The rejection was on the grounds that Claims 24-23, 28 and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. *This is a written description rejection.*

The specification broadly describes as a part of the invention polypeptides that are variants or fragments of SEQ ID No. 11. The specification discloses the claimed invention also contemplates fragments, derivatives and variants (such as allelic variants) of the exemplified proteins (page 13). The specification states " that amino acids can be deleted from any of the C1-5 sequences set forth in Figure 1, while not all non-conserved amino acids in the V1-4 regions need be deleted in order to reduce strain-specific immunogenicity and isolated proteins of the invention may include fragments of the C1-5 and V1-4 regions" (page 13). The specification also states " that a "fragment" includes an amino acid sequence that constitutes less than 100%, but at least 20%, preferably 50%, more preferably at least 80% or even more preferably at least 90% of said C1, C2, C3 C4 or C5 regions". Applicant has broadly described the invention as embracing any substitution, insertion or deletion change of amino acids throughout the length of the polypeptide sequence. Variants or fragments of SEQ ID No: 11 correspond to sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a variant degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 U.S.C. 112, first, paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of allelic variants or fragments of SEQ ID NO: 11 that are encompassed by the polypeptides of the invention regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, the full breadth of the claim (or none of the sequences encompassed by the claim, i.e. variants or fragments of SEQ ID No: 11) does not meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant urges that the Examiner has suggested that the claimed genus is highly variant. Applicant urges that the claimed invention are drawn to an isolated protein comprising amino acids from a conserved region of the consensus sequence, SEQ ID NO:11. Applicant urges that they have discovered minimum sequences that are necessary in an isolated protein that elicits an immune response against multiple (or all) strains of *N. meningitidis*. Applicant urges that because the claim language is open (comprising) the identity of other residues that may be present in the isolated protein is substantially immaterial. Applicant urges that the minimum sequences include at least twelve contiguous residues from one of the conserved regions (C1-C5) of SEQ ID Nos:1-11 and cross-reactive proteins can have additional sequences, but only the Applicants have discovered how little sequence need be included. Applicant urges that the skilled artisan is able to envision the relevant structure of the isolated proteins that are claimed. Applicant urges that the Examiner is focused on potential sequence variability among NhhA polypeptides, allelic variants and the like despite the fact that the claimed invention is directed to the use of conserved regions of NhhA polypeptides.

Applicant's arguments filed October 25, 2002 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing of the record to that the specification is enabled for the full scope of the claims and therefore does not meet the written description requirement as set forth in 35 U.S.C. 112, first paragraph.

Applicant has not shown enablement for sequence that comprise at least twelve contiguous amino acids of a conserved region of SEQ ID NO:11 and one or more variable region amino acids of SEQ ID NO:11. The Examiner disagrees with the Applicant's assertion that "the claim language is open (comprising) the identity of other residues that may be present in the isolated protein is substantially immaterial". The specification has defined "comprise", "comprises" and "comprising" to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers" (pages 10-11). The specification states that "isolated proteins of the invention may include fragments of the C1-C5 (conserved regions) and fragments of V1-V4 (variable regions) (page 13). The specification also discloses that the "a fragment" includes an amino acid sequence that constitutes less than 100%, but at least 20% of conserved regions C1-C5 (page 13). Therefore, the claimed invention includes fragments and variants of the conserved regions of the claimed protein.

While the use of mutagenesis techniques are known in the art, it is not routine in the art to screen for multiple substitutions or multiple modifications of other types and the positions within the polypeptide's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any polypeptide and the result of such modifications is unpredictable based on the instant disclosure. It should be noted that the Applicant admits in their response that "the minimum sequences include at least twelve contiguous residues from one of the conserved regions (C1-C5) of SEQ ID Nos:1-11 and cross-reactive proteins can have additional sequences, but only the Applicants have discovered how little sequence

need be included". The skilled artisan would require guidance to in order to make and use the claimed isolated proteins commensurate in scope with the claims. Therefore, only SEQ ID NO: 11 and not the full breadth of the claim (i.e. variants or fragments of SEQ ID NO:11) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant.

New Grounds of Rejection Necessiated by Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 25, 28 and 30-32 are rejected under 35 U.S.C. 102(e) as anticipated by Peak et al *(U.S. Patent No. 6,197, 312, published March 6, 2001).*

Claims 25, 28 and 30-32 are drawn to an isolated protein comprising at least twelve contiguous amino acids of a conserved region of SEQ ID NO:11, wherein the isolated protein is not a wild-type NhhA polypeptide and wherein the protein is capable of eliciting an immune response against one or more strain of *N. meningitidis*.

Peak et al teach an isolated polypeptide from *Neisseria meningitidis* and pharmaceutical compositions containing the polypeptide (see the Abstract). Peak et al teach pharmaceutical compositions for treating patients against *N. meningitidis* infections which comprises polypeptides, fragments, variants or derivatives and a pharmaceutically acceptable carrier (column 16, lines 6-64). Peak et al teach that the

compositions of the invention may be used as therapeutic or prophylactic vaccines (column 16, lines 65-66). The claimed isolated protein comprising at least twelve contiguous amino acids of a conserved region of SEQ ID NO: 11 (i.e. amino acid residues 109-120) is the same as amino acid residues 105-116 of SEQ ID NO: 5 of the prior art (see attached sequence alignment). The protein, pharmaceutical composition and vaccine of Peak et al appear to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's protein, pharmaceutical composition and vaccine with the protein, pharmaceutical composition and vaccine of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein, pharmaceutical composition and vaccine of the prior art does not possess the same material structural and functional characteristics of the claimed protein, pharmaceutical composition and vaccine). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. No claims allowed.

MARK NAVARRO
PRIMARY EXAMINER

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
January 3, 2003